UNLEARN

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Comment on "AI Accountability Policy Request for Comment" [Docket No. NTIA-2023-0005]

Date:

12 June 2023

To Whom it May Concern:

Unlearn.AI, Inc. (Unlearn) is submitting these comments in response to the April 13th, 2023 publication of the NTIA AI Accountability Request for Comment.

Our mission at Unlearn is to advance AI to eliminate trial and error in medicine, starting with the domain of clinical trials. We innovate rigorous statistical and machine learning methods that enable smaller, more efficient clinical trials, bringing effective medicines to patients sooner. We appreciate that NTIA has solicited responses in developing broader AI policy, and as such, we have provided our responses to selected questions as follows:

Questions & Responses

1. What is the purpose of AI accountability mechanisms such as certifications, audits, and assessments?

We believe the purpose of AI accountability mechanisms is to increase public trust in AI by requiring companies who use and deploy this technology to implement responsible processes for its application. As such, AI accountability mechanisms should be primarily encouraged (and enforced as appropriate) by the specific governmental agency that regulates its context-of-use. For example, AI used within the development and manufacture of drugs, biologics, and medical devices, is currently and should continue to be regulated by the Food and Drug Administration (FDA). Additionally, the level of applicable accountability mechanisms for each use context should also be dependent on the level of risk involved (see V&V 40 for an example within the field of Medical Devices).

2. Is the value of certifications, audits, and assessments mostly to promote trust for external stakeholders or is it to change internal processes? How might the answer influence policy design?

We believe that the value of certifications, audits, and assessments is a combination of both promoting trust in external stakeholders as well as improving internal processes. Risk assessments should be utilized to ensure adherence to regulatory policy and identify improvements to internal controls. Third-party and customer audits should be utilized to assess the effectiveness of those internal controls while certifications should be evidence to show those controls are effective and trusted by

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a regulatory body. As the uses of AI/ML are constantly evolving, there should be a drive for each responsible governmental agency to create policies with the ability to accommodate novel AI/ML applications falling under their authority. We believe that agencies like the FDA are taking the right steps to engage stakeholders in the domain of AI/ML to anticipate the growing regulatory need in this area.

7. Are there ways in which accountability mechanisms are unlikely to further, and might even frustrate, the development of trustworthy AI? Are there accountability mechanisms that unduly impact AI innovation and the competitiveness of U.S. developers?

We believe that accountability mechanisms which place heavy requirements on explainability could limit the development of trustworthy AI systems. From FDA's discussion paper on Using AI/ML in the development of drugs and biological products: "In balancing performance and explainability, it may be important to consider the complexity of the AI/ML model. In situations where complex models (e.g., artificial neural network models) are determined to have similar performance, there may be overall advantages to selecting the more traditional and parsimonious (i.e., fewer parameters) model." While this is intuitive in the situation that similar performance occurs, experimenters and theory over the last 5 years have revealed the phenomenon of "double descent" which, in part, explains how models with many parameters can often generalize better than models with fewer parameters (Belkin et al PNAS 2019). While a more traditional explainable model can seem to be more transparent, it may not always achieve the performance level, nor the generalizability, required for a given context-of-use. In this manner, prioritization of explainability could restrict the development of more powerful models that enable greater accuracy. Thus, the emphasis on individual accountability mechanisms should be titered according to risk and use case, which puts the onus of assigning these accountability mechanisms in the hands of individual governmental agencies.

10. What are the best definitions of terms frequently used in accountability policies, such as fair, safe, effective, transparent, and trustworthy? Where can terms have the same meanings across sectors and jurisdictions? Where do terms necessarily have different meanings depending on the jurisdiction, sector, or use case?

We believe that the definitions for terms frequently used in accountability policies are too general and should be utilized only as appropriate in a given sector, as different use cases should have different requirements to be considered fair, safe, effective, transparent, and trustworthy. For example, drug manufacturers have an understandable business priority to keep certain formulations/trade secrets confidential, and while the FDA can still request these details for review, they do not reveal them publicly. In the implementation of transparency-related policies, there needs to be consideration of intellectual property and context-of-use, particularly in

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terms of risk assessment.

17. How should AI accountability measures be scoped (whether voluntary or mandatory) depending on the risk of the technology and/or of the deployment context? If so, how should risk be calculated and by whom?

Agencies already working to regulate a given industrial sector have been and should be able to continue to be trusted to characterize the level of risk of technological implementation in that sector.

24. What are the most significant barriers to effective AI accountability in the private sector, including barriers to independent AI audits, whether cooperative or adversarial? What are the best strategies and interventions to overcome these barriers?

We believe the most significant barriers to effective AI accountability in the private sector revolve around proprietary technology associated with an organization's AI use case. Protecting the IP associated with an organization's AI use case is critical to retain value for those who have developed novel AI technologies, but it can also be viewed as a barrier to transparency and public trust. As such, the best strategy would be for regulatory agencies in each sector to establish an appropriate risk-based framework for AI as applicable to the use contexts within that sector.

30. What role should government policy have, if any, in the AI accountability ecosystem? For example: a. Should AI accountability policies and/or regulation be sectoral or horizontal, or some combination of the two?

We believe that government policy in the AI accountability ecosystem should be sectoral according to the context-of-use associated with the AI technology. This is because various AI use-cases have differing amounts of risk associated with their utilization and should be subject to accountability mechanisms in accordance with that level of risk. Furthermore, the same AI technologies could be applied in different industries that have vastly different implications for risk assessment (for example, consider large language models being used to write advertising copy versus those used to diagnose patients). Agencies already working to regulate a given industrial sector should be trusted to characterize the level of risk of technological implementation in that sector, preventing overregulation.

34. Is it important that there be uniformity of AI accountability requirements and/or practices across the United States? Across global jurisdictions? If so, is it important only within a sector or across sectors? What is the best way to achieve it? Alternatively, is harmonization or interoperability sufficient and what is the best way to achieve that?

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We believe that there should be uniformity of AI accountability requirements within respective sectors according to the use cases, and subsequent risk, of the specific AI technologies utilized therein. If accountability requirements were applied uniformly across all sectors of industry in the US, it could result in inappropriately strict requirements that fetter the pace of innovation.

Thank you for taking the time to review our comment on this draft guidance.

Best regards,

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